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10/631,228	07/31/2003	Jaya Pathak	50623.251	1730
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/631,228

Applicant(s)

PATHAK ET AL.

Examiner

Jimmy Lin

Art Unit

1792

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-14,16-29 and 31-37 is/are pending in the application.
- 4a) Of the above claim(s) 7,11,12,14 and 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,8-10,13,16-18,23-29 and 31-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-848)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 10, 18, and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Although a variety of fluids are exemplified in the specification as representative fluids, there is no teaching that any or all of these fluids are of the type to physically entrap an impurity without dissolving the impurity (see pg. 8-9). Thus, the claims present new matter.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan et al. (U.S. Publication 2004/0063663) in view of Inoue et al. (U.S. Patent 5,762,944) and Hughes et al. (U.S. Patent 5,756,659).

The rejection is cited in the Office Action filed 7/3/2007.

5. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan '663 in view of Inoue '944, and Hughes '659, as applied to claim 31 above, and further in view of Roorda et al. (U.S. Patent No. 2005/0106203).

The rejection is cited in the Office Action filed 7/3/2007.

6. Claims 1, 3-5, 8-10, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan '663 in view of Inoue '944, Hughes '659, and Goodson et al. (U.S. Patent No. 4,117,714).

Buchanan discloses a method of making a carrier polymer that is used to coat the surface of a stent to provide controlled and sustained release of an anticoagulant drug at the preferred site [0065]. The coating can be formed by putting the carrier polymer along with the other additives into a twin screw extruder [0051]. The polymer can be a thermoplastic material [0059].

Buchanan does not teach introducing a fluid into the extruder and removing at least a volume of the fluid from the extruder such that an impurity is at least partially removed with the fluid.

Inoue teaches a method of making a coating for a stent, wherein the coating comprises a polymer (col. 3, lines 1-31). Inoue recognizes the need to wash the polymer to remove impurities in the method of making medical devices such as a stent. The impurities can include a solvent, an unreacted monomer, and an impurity (col. 6, lines 38-43). Hughes teaches a method of removing impurities, such as unreacted monomer, solvent, and thermally unstable species, from a molten polymer inside a twin-screw extruder. A stripping agent is introduced into the polymer melt stream and the polymer/stripping agent mixture is homogenized in a mixing zone. At least some of the stripping agent and impurities are removed from the polymer (col. 3, lines 10-33; Fig. 2). 3) The temperature of each extruder zone is controlled by a temperature controller and resistance heaters that are monitored by means of a series of thermocouples 29-36 (col. 3, lines 16-20). The temperatures of the thermocouples range from 112 to 240 °C (Table 6). It would have been obvious to one of ordinary skill in the art at the time of invention to have introduced a fluid into the extruder to have removed impurities from the polymer of Buchanan because Inoue recognizes the need to remove impurities in a method of making a material for a medical device and because Hughes teaches that such an in-situ process is suitable in the art of removing impurities from a polymer. The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945).

Buchanan, Inoue, and Hughes do not explicitly teach that the fluid is a type to physically entrap the impurity without dissolving the impurity. However, Goodson teaches that there are

only a finite number of identified, predictable potential solutions in the method of removing impurities. Specifically, Goodson teaches that an impurity can be removed from a medium by either dissolving or entrapping the impurity in a fluid (col. 3, lines 39-42). One of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success (see MPEP 2145.X.B.). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have used a fluid to physically entrap the impurity, as opposed to a fluid to dissolve the impurity, in the method removing the impurity of Buchanan with a reasonable expectation of success and with predictable results.

Claim 3: Buchanan teaches that a single screw extruder can also be used [0051].

Claim 4-5: Buchanan teaches that the polymer must be melted in the extruder [0051].

Claim 8: Hughes teaches that a second stripping agent can be introduced to the extruder, wherein the stripping agent removes an impurity from the polymer (col. 3, lines 33-45).

Claim 9: Buchanan teaches that a suitable thermoplastic can be polyethylene-vinyl acetate copolymer (i.e., an ethylene-vinyl acetate copolymer) [0059].

Claim 10: Inoue teaches that a suitable solvent can be acetone (col. 6, lines 38-43).

Claim 35: Hughes teaches that the fluid is exposed to temperatures ranging from 112 °C to 240 °C (Table 6).

7. Claims 13, 16-18, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan '663, Inoue '944, Hughes '659, and Goodson '714, as applied to claim 1 above, and further in view of Berg et al. (EP 0623354).

Buchanan, Inoue, and Hughes are discussed above, but do not explicitly teach that the polymer can be combined with a solvent. However, Berg teaches that a solution comprising a polymer and solvent can be applied to the coating of a stent and then evaporating the solvent (abstract). The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have applied the polymer of Buchanan, Inoue, and Hughes in a solvent solution and then evaporating the solvent because Berg teaches that such a coating method is suitable in the art of coating a stent.

Claim 36: Buchanan, Inoue, and Hughes do not explicitly teach introducing a second fluid that is of a type that dissolves the impurity. However, Hughes does teach that a second fluid is introduced to remove impurities and Goodson teaches that there are only a limited, potential solutions for removing impurities from a medium. One of ordinary skill in the art would have recognized that the use of a fluid having the properties either to entrap or to dissolve an impurity as the particular second fluid would have been operable and that the use of one over the other would have yielded predictable results. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have used a fluid that is of a type that dissolves an impurity, as opposed to one that entraps an impurity, as the particular second fluid of Hughes with a reasonable expectation of success.

Claims 16-18 and 37 are rejected for substantially the same reasons as claims 4-5, 9-10, and 35 above.

8. Claims 23-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan '663 in view of Inoue '944, Hughes '659, and Goodson '714, as applied to claim 1, and further in view of Greff et al. (U.S. Publication No. 2001/0009656) and Neoh et al. (U.S. Publication No. 2002/0031616).

Buchanan, Inoue, and Hughes are discussed above, but do not explicitly teach that the fluid is selected from FLUX REMOVER AMS, dimethyl acetamide, dimethyl formamide, cyclohexane, dimethyl sulfoxide, and combinations thereof.

Buchanan does not teach the specifics of how the polymers are formed. However, Greff teaches that it was well known in the art to polymerize monomers and oligomers to form the desired polymer [0077],[0090]. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have polymerized monomers to produce the polymers of Buchanan with a reasonable expectation of success because Greff teaches that such methods of forming polymers were operable in the art.

Inoue teaches the need to remove unreacted monomers from the polymer composition. Accordingly, Neoh teaches that it was well known to use dimethyl formamide (DMF) to remove unreacted monomer [0065]. Because Inoue teaches the need to remove unreacted monomers and Neoh teaches such fluids were operable to remove unreacted monomers, it would have been

obvious to one of ordinary skill in the art at the time of invention to have used DMF as the particular fluid to remove the impurities in the polymer composition of Buchanan with a reasonable expectation of success.

9. Claims 23-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan '663 in view of Inoue '944, Hughes '659, and Goodson '714, as applied to claim 1, and further in view of Bernstein et al. (U.S. Publication No. 2001/0000230).

Buchanan, Inoue, and Hughes are discussed above, but do not explicitly teach that the fluid is selected from FLUX REMOVER AMS, dimethyl acetamide, dimethyl formamide, cyclohexane, dimethyl sulfoxide, and combinations thereof. However, Bernstein teaches that it was well known that DMF was rated as a class 3 residual solvent by the FDA [0020]. One of ordinary skill in the art would have recognized that the use of a solvent that had a high safety rating would have produced a medical implantation device that would reduce the harmful effects of any residual solvent remaining in the polymer of Buchanan. Because Inoue teaches that other solvents can be used and because Bernstein teaches that DMF had a high safety rating, it would have been obvious to one of ordinary skill in the art at the time of invention to have used DMF as the particular solvent to remove the impurities of Buchanan with a reasonable expectation of success.

Response to Arguments

10. Applicant's arguments filed 11/27/2007 have been fully considered but they are not persuasive.

Claims as rejected over Buchanan '663, Inoue '944, and Hughes '659:

Applicant argues on pg. 10-11 that Examiner has provided no support or explanation as to why an organic solvent or water of Inoue must necessarily physically entrap monomers and would not dissolve the monomers. However, Goodson teaches that there are only a finite number of identified, predictable potential solutions for solving the problem of removing impurities, as discussed above. Pursuing the limited number known solutions would have been obvious. The teachings of Goodson have been added to the rejection to address the added limitations.

Applicant argues on pg. 11 that none of the cited references recognize a distinction between using a combination of a solvent and a non-solvent. However, the present specification indicates that water can act as both a solvent and a non-solvent (see paragraph bridging pg. 8-9) and Inoue teaches that water can be used as a fluid to remove impurities. Thus, the use of water would have necessarily acted as non-solvent in the removal of at least some of the impurities of Buchanan. Because Hughes teaches that two fluids can be used in the removal of impurities, one of ordinary skill in the art would have used any two fluids from the list of operable fluids as taught by Inoue, including the use of water as one of the particular fluids, with a reasonable expectation of success.

Claims as rejected over Buchanan, Inoue, Hughes and Roorda:

Applicant argues on pg. 12 that the cited references fail to teach that the fluid is selected from the group consisting of FLUX REMOVER AMS, dimethyl acetamide, dimethyl formamide, cyclohexane, dimethyl sulfoxide, and combinations thereof. However, the use of dimethyl formamide (DMF) would have been obvious over Greff and Neoh, as discussed above. Additionally, Bernstein teaches that DMF has a high safety rating as a residual solvent. One of ordinary skill would have used safer solvents in the method of making a medical device in the case that residual solvent would remain in the polymer of the device.

Applicant argues on pg. 12 that claim 28 requires the fluid to be a type to physically entrap the impurity without dissolving the impurity and that the cited references do not teach such limitations. However, the claim lacks support from the specification because the specification does not teach that the fluids listed in claim 23 are of the type to physically entrap the impurity without dissolving the impurity.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Iguchi et al. (U.S. Patent 5,756,553) recognizes the need to remove impurities from polymers used for medical devices (col. 4, line 66 – col. 5, line 2).

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy Lin whose telephone number is (571)272-8902. The examiner can normally be reached on Monday thru Friday 8AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy H Meeks/
Supervisory Patent Examiner, Art Unit 1792

/Jimmy Lin/
Examiner, Art Unit 1792